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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,001	05/01/2002	Mark A Samuels	19141.0035U3	7089

23859 7590 09/24/2003

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EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/24/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,001

Applicant(s)

SAMUELS ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The request to correct the inventorship of this nonprovisional application under 37 CFR 1.48(a) is deficient because: An oath or declaration by each actual inventor or inventors listing the entire inventive entity has not been submitted. The oath or declaration lists the inventors on three separate pages and some pages have been copied with different inventors signing different copies. It is not clear if all the inventors were aware of the entire listing of the inventive entity when signing the declaration. For example, it is not clear if the inventors who signed the various copies of the first page were aware of the inventors listed on the second and third pages or if the inventors who signed the various copies of the second page were aware of the inventors listed on the third page.

Election/Restrictions

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

First Collection of Species:

Species A, shown in Fig. 1B, drawn to a system with a tissue breaching device using an energy emitter.

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Species B, shown in Fig. 1C, drawn to a system with a tissue breaching device using heated elements.

Species C, shown in Fig. 1D, drawn to a system with a tissue breaching device using mechanical means.

Second Collection of Species:

Species I, shown in Figs. 2A-C, drawn to a system in which the alignment device uses a clip.

Species II, shown in Fig. 3, drawn to a system in which the alignment device uses threaded members.

Species III, shown in Figs. 4A-E, drawn to a system in which the alignment device includes energy absorbing layers used in laser ablation.

Species IV, shown in Fig. 5, drawn to a system in which the alignment device uses geometric-shaped interfaces.

Species V, shown in Fig. 6, drawn to a system in which the tissue interface member has 1 female member.

Species VI, shown in Fig. 7, drawn to a system in which the tissue interface member has 1 male member.

Species VII drawn to a system in which the alignment device uses magnetic surface portions.

Applicant is required, in reply to this action, to elect a single species from each collection to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species,

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including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. The claims are deemed to correspond to the species listed above in the following manner:

First Collection of Species

Species A: claims 2-5, 17-20, 24-28, 33-40, and 42

Species B: claims 22, 24, and 33

Species C: claims 21, 24, and 33

Second Collection of Species

Species I: claims 6-7 and 9

Species II: claims 10 and 13

Species III: claims 2-5 and 9

Species IV: claims 9-10

Species V: claims 9 and 11

Species VI: claims 10 and 11

Species VII: claim 12

The following claim(s) are generic: 1, 8, 14-16, 23, 29-32, and 41.

6, 7, 10-13, 21, 22

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4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. Species A-C involve different methods of tissue breaching for obtaining fluid samples. Species I-VII involve different methods of attachment to the alignment device.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. A telephone call was made to Jennifer Medlin on 8/14/2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer
Assistant Examiner
Art Unit 3736
September 16, 2003



ERIC F. WINAKUR
PRIMARY EXAMINER